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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/828,351

04/21/2004

Manja Ahola

TUR-140-A

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05/17/2006

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EXAMINER

TRAN, SUSAN T

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 05/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/828,351 | AHOLA ET AL. | |
| | Examiner | Art Unit | |
| | Susan T. Tran | 1615 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-28 and 31 is/are rejected.
- 7) ☒ Claim(s) 29 and 30 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Terminal Disclaimer

The terminal disclaimer filed on 02/24/06 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of USPN 6,764,690 has been reviewed and is accepted. The terminal disclaimer has been recorded. Accordingly, the obviousness-type double patenting rejection has been withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 23-28 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ducheyne et al. US 5,591,453, in view of Einarsrud et al. US WO 92/20623.

Ducheyne teaches a controlled release matrix carrier comprising silica based glass prepared by a sol-gel process (see abstract; and column 8, lines 43-67). The silica based glass further comprising calcium (column 10, lines 8-10). Ducheyne further teaches biologically active molecules are incorporated within the matrix (see abstract). Biologically active molecules include drugs, growth factors, cytokines, antibiotics, anti-inflammatory agent, and analgesics (column 9, lines 54-64). Ducheyne also teaches the matrix is suitable for administration as an implant in the form of granules, discs, or monoliths (column 10, lines 8-16).

Ducheyne does not teach the silica-xerogel. However, silica-xerogel is well known as silica based glass compound in pharmaceutical art. To be more specific, Einarsrud teaches silica-xerogel has high porosity and therefore suitable to be used as a composite material and carrier for catalyst and liquids (page 1, lines 25-27). Thus, it would have been obvious to one of ordinary skill in the art to modify the teaching of Ducheyne using the silica-xerogel as a silica based glass to obtain the claimed invention, because Ducheyne teaches the use of silica based glass in a composite composition (column 6, lines 32-34), because Ducheyne teaches the desire to use porous material (column 10, lines 8-21), because Ducheyne teaches using a sol-gel process to obtain a microporosity sol-gel glass that can control the release of the biologically active molecules (column 9, lines 5-19), because Ducheyne teaches silica-based includes silicon oxide, and other oxides (column 9, lines 50-52), and because Einarsrud teaches using high porosity material such as silica xerogel as a composite material.

Response to Arguments

Applicant's arguments filed 02/24/06 have been fully considered but they are not persuasive.

Applicant argues that Ducheyne fails to disclose the total dissolution feature of the claimed method, wherein the silica-xerogel dissolves controllably, and release of the biologically active agent from the silica-xerogel is determined by this silica-xerogel dissolution. Thus, the release of bioactive agent is substantially independent of diffusion through the pores of the silica-xerogel. Instead, Ducheyne teaches a release rate that is primarily by diffusion of its bioactive agent through the pores of its silica-based gel.

However, in response to applicant's argument, it is noted that the instant claims do not preclude the bioactive agent to release through the pores of the silica-based gel. Nor, do the instant claims require a total dissolution of the bioactive agent by dissolving the silica-xerogel to completely release the bioactive agent in a very even fashion. Applicant's attention is called to the teaching at column 14, lines 14-37, Ducheyne teaches in order for sol-gel to be an effective carrier for biologically active molecules, sol pH and other factors affect the gelling time of the sol...there are instances when greater porosity may be desirable to achieve a more rapid degradation of the carrier to facilitate the release of larger molecules. Thus, it would have been obvious to one of ordinary skill in the art to modify the porosity of the gel to obtain the desired release rate.

Applicant argues that Ducheyne does not disclose carrier degradation or biodegradation as its primary release mechanism. In response to applicant's argument

Art Unit: 1615

that the reference does not show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., carrier degradation or biodegradation as its primary release mechanism) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant argues that the deficiencies of Ducheyne are not remedied by the additional disclosure of Einarsrud, because Einarsrud does not teach the complete dissolution feature of the claimed method of administering a biologically active agent into a human or animal body, but its main emphasis is on obtaining gels with high porosity. In response to applicant's argument, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In the instant case, Einarsrud is relied upon solely for the teaching that silica-xerogel can be used as a composite materials or carrier due to its porosity (page 1, lines 21-27).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1615

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Claims Allowable

Claims 29 and 30 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on Monday through Thursday 6:00 am to 4:30 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone

Art Unit: 1615

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

S. Tran
Patent Examiner
Art Unit 1615



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